

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A composition for improving the bioavailability of a drug comprising at least one poorly bioavailable drug dissolved in an effective amount of menthol, wherein the effective amount of menthol is about 20% to about 99% by weight of the composition.
2. (original) The composition according to claim 1, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug metabolized by cytochrome P450, a drug expelled from cells by the P-glycoprotein pump, or a drug metabolized via glucuronidation.
3. (original) The composition according to claim 2, wherein the drug with low aqueous solubility is a drug having a water solubility of less than about 20 mg/ per milliliter of water.
4. (original) The composition according to claim 1, wherein the drug is cyclosporine, atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, simvastatin, paclitaxel, fenofibrate, itraconazole, bromocriptine, carbamazepine, diazepam, paclitaxel, etoposide, camptothecin, danazole, progesterone, nitrofurantoin, estradiol, estrone, oxfendazole, proquazone, ketoprofen, nifedipine, verapamil, or glyburide.
5. (original) The composition according to claim 1, wherein the drug is cyclosporine, atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, simvastatin, or paclitxel.
6. (original) The composition according to claim 1, wherein the compound is simvastatin, paclitaxel, or cyclosporine.
7. (original) A method for improving the bioavailability of a drug comprising dissolving the drug in an effective amount of menthol.

8. (currently amended) A method for improving the bioavailability of a drug comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is about 20% to about 99% by weight of the solution.

9. (original) The method according to claim 8, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

10. (original) The method according to claim 8, further comprising administering the composition to a mammal.

11. (original) The method according to claim 8, wherein the amount of menthol is sufficient to increase the oral bioavailability of the drug by an amount represented by an about 10% or more increase in the average area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

12. (original) The method according to claim 9, wherein the amount of menthol is about 60% to 99% by weight.

13. (currently amended) A method for reducing the variability of the bioavailability of a drug comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is sufficient to decrease the variability in the drug's bioavailability by about 10% or more of the relative standard deviation (CV%) of the area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

14. (original) The method according to claim 13, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

15. (original) The method according to claim 13, further comprising administering the composition to a mammal.

16. (currently amended) The method according to claim 13, wherein the amount of menthol is sufficient to decrease the variability in the drug's bioavailability by about ~~40%~~ 50% or more of the relative standard deviation (CV%) of the area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

17. (currently amended) A method for increasing the extent of time that a drug provides a therapeutically significant concentration in blood or plasma comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol, wherein the effective amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more.

18. (original) The method according to claim 17, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

19. (original) The method according to claim 17 wherein the amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more.

20. (new) The composition of claim 1, wherein the improvement in bioavailability is determined as at least a 5% increase in the ratio of AUC_t/AUC_r above 100%.

21. (new) The method of claim 8, wherein the improvement in bioavailability is determined as at least a 5% increase in the ratio of AUC_t/AUC_r above 100%.